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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/500,376	02/08/00	CHANG S	A-67984/RFT/

HM22/0815
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EXAMINER	
FIELDS, I	
ART UNIT	PAPER NUMBER
1645	11

DATE MAILED: 08/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/500,376	CHANG ET AL.	
	Examiner	Art Unit	
	Iesha P Fields	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 37-55 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Applicant's Preliminary Amendment (Paper No.6) filed September 25, 2000, has been entered and received. Claims 1-36 have been canceled according to Applicant's request. New claims 37-55 have been added.

Priority

If applicant desires priority under 35 U.S.C. based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Oath/Declaration

It does not identify the post office address of each inventor. A post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The post office address should include the ZIP Code designation.

Drawings

This application has been filed with informal drawings which are acceptable for examination purposes only. Correction of the noted defects can be deferred until the application is allowed by the examiner.

Claim Rejections - 35 USC § 112

1. Claims 50-55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a making an immunogenic composition comprising p42 polypeptide, it does not reasonably provide enablement for making an "anti-plasmodium" vaccine.

It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A. et al., (ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies... and thus protect the host against attack by the pathogen." Since no working examples are set forth in the specification that the claimed species is useful for vaccination and the art teaches of the unpredictability of using a single antigen for vaccination it would be an undue burden and be unpredictable to use the broadly claimed product for vaccination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

2. Claims 37-38 and 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holder et al further in view of Soltysik and Saul et al .

The claims are drawn to a pharmaceutical composition comprising p42 polypeptide and an adjuvant.

Holder et al. (Nature 1985 Vol. 317 (6034) pp. 270-73) teach of the sequence of merozoite major surface antigens (83 KD, 42 KD and 19KD) isolated from *Plasmodium falciparum.*

Holder et al. does not teach of a pharmaceutical composition comprising p42 polypeptide and an adjuvant such as QS-21 or ISA51.

Soltysik (Vaccine 1995 Vol. 13(15) pp. 1403-1410) teach of the use of Quilaja saponaria (QS-21) as an immunologic adjuvant.

Saul et al. (Second African Malaria Vaccine Testing Network Meeting, Accra, Ghana, November 24-26 1997) teach of an immunogenic composition of 3 recombinant asexual stage malaria antigens including MSP-1 administered to humans. Saul et al. further teach that the composition comprises p42 polypeptide and Montanide ISA adjuvant.

Given that 1) Holder et al. has taught of the p42 polypetide of *P. falciparum* and that 2) Soltysik et al. has taught of the use of QS-21 as an immunologic adjuvant and that 3) Saul et al. has taught of administering MSP1 and Montanide ISA adjuvant it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a pharmaceutical composition comprising p42 polypeptide and an adjuvant such as QS-1 or Montanide ISA. One would have been motivated to make such a composition in view of the teachings of Saul et al. that immunogenic compositions comprising adjuvants such as Montanide ISA720 have shown a greater immune response when compared to immunogenic compositions using traditional adjuvants such as alum.

3. Claims 37 and 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holder et al further in view of Murphy and Smith et al .

The claims are drawn to a pharmaceutical composition comprising p42 polypeptide expressed by an insect cell containing a vector encoding the polypeptide.

The teachings of Holder are set forth above.

Holder does not teach of a pharmaceutical composition comprising p42 expressed by an insect cell containing a vector encoding the p42 polypeptide.

Smith et al. (US Patent 4,745,051) teach of a recombinant baculovirus expression vector, capable of expressing a selected gene in a host insect cell.

Murphy et al. (Parasitology 1990 Vol. 2 pp.177-83) teach of recombinantly produced p42 antigen of the Wellcome isolate of gp195 in insect host cells.

Given that 1) Holder et al. has taught of the p42polypetide of *P. falciparum* and that 2) Murphy and Smith et al. have taught of recombinant expression vectors capable of expressing a selected gene in a host insect cell and that 3) Murphy et al. has taught of a recombinantly produced p42 antigen of the Wellcome isolate of gp195 in insect host cells it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to make a pharmaceutical composition comprising p42 polypeptide expressed by an insect cell containing a vector encoding the polypeptide. One would have been motivated to make such a composition in view of the teachings of Murphy et al. that product obtained folds in similar manner as the natural antigen. Therefore one of ordinary skill in the art would reasonable expect that product taught by Murphy et al. would be suitable for a pharmaceutical composition.

Status of Claims

4. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

August 13, 2001

MARK NAVARRO
PRIMARY EXAMINER